Reviewer's report

Title: Questioning participants in antimalarial and antiretroviral interaction trials to obtain adverse event, medical history and concomitant medication data: a mixed method study illustrating how responses are influenced by a trial's social context.

Version: 1 Date: 6 June 2013

Reviewer: Sassy S Molyneux

Reviewer's report:

This is a generally well written paper on a topic of relevance to conducting clinical trials; and very appropriate in my view for BMC Medical Research Methodology.

I do not have any major required changes, but have to minor suggestions for consideration by the authors:

• Make more of the figure that summarises responses, as a framework to build on in future studies and to make considerations about the level of detail/methodology that might be most appropriate for particular studies/trials. This could be in the title, abstract and in the discussion
• Reduce the conclusion section to something shorter and more punchy, by removing detailed practical implications and inserting these instead into the discussion (which could include sub-headings).
• There is another limitation I think that is worth noting: that differences in findings by context may have been influenced by the interviewer (as well as the numerous other potential influences they note).
• The time difference between checklists and in-depth interviews and focus group discussions should be added into the methods section.
• Carefully re-read the entire paper to strengthen readability, and to clarify some wording. Some examples of sentences that need amending when read with fresh eyes:
  o Background para 3 last line on nocebo effects – explain
  o Study population line one
  o Safety data reports – para 3 – penultimate sentence unclear
  o First and second sentence of’ results from the trial participants’ narratives’ unclear
  o Under trial citizenship in South African inpatient volunteers – para two (after first quote in that section), it becomes unclear which setting is being described
  o Check last sentence before discussion
  o Typo in para 4 of discussion
  o In several places interviews has a gap before the s
1. Is the question posed by the authors well defined? 
   Yes

2. Are the methods appropriate and well described? 
   Yes, there are limitations but these have been outlined in a limitations section

3. Are the data sound? 
   Yes

4. Does the manuscript adhere to the relevant standards for reporting and data deposition? 
   Yes

5. Are the discussion and conclusions well balanced and adequately supported by the data? 
   Yes, they highlight that

6. Are limitations of the work clearly stated? 
   Yes

7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished? 
   Yes

8. Do the title and abstract accurately convey what has been found? 
   Yes

9. Is the writing acceptable? 
   Yes

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests